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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/215,569

Applicant(s)

Bier et al.

Examiner

David Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) 3-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The amendment filed 05/14/2001 (Paper No. 14) has been entered. Claims 1-26 are pending.

2. Applicant's election with traverse of group I, claims 1, 2, in Paper No. 14 is  
5 acknowledged. The traversal is on the ground(s) that MPEP 803.04 makes clear that restriction between the nucleotide sequences cannot be required. This is not found persuasive because nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the  
10 contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 Applicant has offered no evidence contrary to the presumption that each claimed nucleotide sequence represents an independent and distinct invention. Furthermore, "one" is "up to ten".

The traversal is on the ground(s) that the same reasoning that supports the partial waver  
15 of 37 CFR 1.141 as to nucleotide sequences also applies to peptide sequences. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed invention if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05(i)). The polynucleotides,

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polypeptides, methods, and antibodies are distinct for the reasons given in the Office action mailed 03/20/2001 (Paper No. 13). Furthermore, separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions imposes a serious burden upon the Examiner. See M.P.E.P. § 803. Such  
5 separate classification is set forth in the Office action mailed 03/20/2001. Polynucleotide and polypeptide searches are not coextensive as indicated by their separate classification. Applicant has offered no evidence to rebut this showing.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 3-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as  
10 being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

4. Claims 1 and 2 are being examined.

5. The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, 37 C.F.R. § 1.821 (d) which states "Where the description or claims of a  
15 patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence

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identifier, preceded by "SEQ ID NO: " in the text of the description or claims." The application and claim 1 reference sequences by use of the sequence identifier, preceded by "SEQ.ID.No.". "SEQ.ID.No." should be "SEQ ID NO: ".

Correction is required.

- 5      6.      The GenBank Accession numbers cited on the information disclosure statement have been considered to the extent possible. However, a residue by residue comparison has not been done.

***Claim Rejections - 35 USC § 101***

7.      35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15

8.      Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The polynucleotide as claimed reads on a product as it occurs in nature, without the hand of man. It is suggested that the claim be limited to an isolated or purified polynucleotide.

***Claim Rejections - 35 USC § 112***

9.      The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 are indefinite because it is unclear if the polynucleotide of claim 1 comprises the same nucleotide composition as the nucleotide composition of SEQ ID NO: 1 or if it comprises the nucleotide sequence of SEQ ID NO: 1. The metes and bounds of the claim(s) are not clearly set forth. It is suggested that the claims recite "comprising the nucleotide sequence of SEQ ID NO: 1".

### *Specification*

11. The amendment filed 12/22/2000 (Paper No. 11, the response to the notice to comply) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the paper copy and computer readable form of the sequence listing are not supported by the original disclosure because the sequences in the figures in the original disclosure are illegible, unreadable,

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and indecipherable and there is no basis in the original disclosure for the sequences in the paper copy and computer readable form of the sequence listing.

Applicant is required to cancel the new matter in the reply to this Office action.

***Conclusion***

5      12.      No claims are allowable.

13.      The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marques (u15)<sup>1</sup> teaches that the TLD protein is able to cleave SOG (paragraph bridging pages 421-422 and Figure 5).

10      ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

15      OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

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<sup>1</sup>Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING  
SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

*David Romeo*

DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

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JULY 16, 2001